## JAP15 Rec'd PCT/PTO 2 0 APR 2006 Atty. Dkt. No. 037775-0107

#### IN THE UNITED STATES PATENT AN D TRADEMARK OFFICE

Applicant:

Robyn WARD et al.

Title:

ASSESSMENT OF DISEASE RISK BY QUANTITATIVE DETERMINATION OF EPIMUTATION IN NORMAL TISSUES

Int'l, Appl. No.: PCT/AU2004/001434

Int'l, Filing Date:

10/20/2004

Examiner:

Unassigned

Art Unit:

Unassigned

### INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §1.56

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a prima facie art reference against the claims of the present application.

### TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), within three (3) months of the filing date of the application.

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#### RELEVANCE OF EACH DOCUMENT

The documents being cited in the attached PTO/SB/08 were cited as being relevant during the prosecution of the corresponding international application. A copy of the International Search Report is attached setting forth the portion of the documents considered relevant by the examiner. A copy of the cited references listed in the Search Report are not being submitted herewith.

Applicants respectfully request that each listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date 20 April 2006

FOLEY & LARDNER LLP Customer Number: 22428 Telephone: (202) 672-5404

Facsimile: (202) 672-5399

Stephen A. Bent Attorney for Applicant Registration No. 29,768

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MODIFIED PTO/SB/08 (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number. Complete if Known Substitute for form 1449B/PTO INFORMATION DISCLOSURE Application Number April 20, 2006 Filing Date STATEMENT BY APPLICANT First Named Inventor Robyn Lynne WARD Date Submitted: April 20, 2006 1634 Group Art Unit Umassigned Amanda Shaw (use as many sheets as necessary) **Examiner Name** 037775-0107 Sheet 1 of Attorney Docket Number

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite	U.S. Patent Document		Name of Patentee or Applicant of Cited	Date of Publication of	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	No.1	Number	Kind Code <sup>2</sup> (if known)	Document	Cited Document MM-DD-YYYY	Figures Appear
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FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No.1	Foreign Patent Document  Office <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if Incom)	Name of Patentee or Applicant of Cited Documents	Date of Publication of Gited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Ţ6
	A1	W0 2000/026401 A	THE JOHNS HOPKINS UNIVERSITY	5/11/2000		
			SCHOOL OF MEDICINE			

	-	NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No.1					
***************************************	A2	C.R. HOLST et al., "Methylation of p16 <sup>NK4</sup> a promoters occurs in vivo in histologically normal human mammary epithelia", Cancer Research 63, 1596-1601, April 2003.				
	A3	H. NAKAYAMA et al., "Molecular detection of p16 promoter methylation in the serum of colorectal cancer patients", Cancer Letters, 188, pp. 113-113-2002.				
-	A4	S.A. KUISMANEN et al., "Genetic and epigenetic modification of MLH1 accounts for a major share of microsatelite-unstable colorectal cancers", American bound of hambody 150(19)(2000), pp. 1979–1979.				
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## ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.S./

Examiner	4. 4.01.4	Date	03/00/2010
Signature	/Amanda Shaw/	Considered	03/09/2010

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique clation designation number "See attached Kinds of U.S. Patient Documents." Either Office that issued the document, by the two-letter code (WIPO Standard ST.) "Or Japanese patient document, but indication of the year of the reight of the Emporr must precede the serial number beant document. "Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. "Applicant is to place a check mark here if English language Translation is eathered.

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